American
Clinical Laboratory
Association

September 4, 2012

Ms. Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1590-P; Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for CY 2013 – Proposed Rule

Dear Ms. Tavenner:

The American Clinical Laboratory Association ("ACLA") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS's" or "the agency's") Proposed Rule on revisions to the Physician Fee Schedule ("PFS") for CY 2013 ("Proposed Rule").[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies will be impacted directly by the Proposed Rule.

I. Summary of ACLA's Comments

Payment for Molecular Pathology Services: The majority of ACLA's comments on the PFS Proposed Rule concern payment for molecular pathology services. CMS has paid for molecular pathology tests furnished by clinical laboratories for two decades under the Clinical Laboratory Fee Schedule ("CLFS"). The new CPT codes about which CMS is soliciting input are just that: new codes to describe those molecular pathology tests. The utility of, and methodology for, these tests remains the same and does not call for shifting all of the tests to the PFS. Each of the tests' results requires some kind of interpretation, and most often, that interpretation is done by a Ph.D. geneticist and does not require the medical judgment of a physician. Occasionally, a pathologist may furnish the interpretation portion of such a test. ACLA believes that all of the molecular pathology tests described by the new CPT codes should continue to be paid for under the CLFS, and in those instances when a pathologist may furnish an interpretation that is in addition to the clinical laboratory service, the interpretation should be payable using the corresponding code on the CLFS with a "-26" modifier that is valued under the PFS.

"TC Grandfather": ACLA once again requests that CMS implement administratively the "TC grandfather" clause, which Congress extended legislatively for several years and which

[1] 77 Fed. Reg. 44,722 (Jul. 30, 2012).

recently expired, so that laboratories will continue to be permitted to bill Medicare for the technical component of a service furnished to a hospital patient when a hospital has a prior arrangement with the independent laboratory for such service.

Physician Signature: In the Information Collection Requirements section of the PFS, CMS seems to have inadvertently included verbiage that would require a laboratory requisition or order to be signed by the physician or non-physician practitioner who orders a laboratory service. ACLA maintains its steadfast opposition to any such blanket requirement for laboratory orders. We believe this statement was an error, and we request that CMS clarify that point to avoid any confusion in the future.

In-Office Ancillary Services: Finally, ACLA is disappointed that CMS once again has failed to act to curb the proliferation of anatomic pathology services furnished pursuant to the Physician Self-Referral Law "in-office ancillary services" exception. Each year that CMS does not address this abusive practice is a tacit signal that the agency will not stop those who engage in it, and it places patients and the Medicare program at risk.

II. Payment for Molecular Pathology Services

The 2012 and 2013 CPT Code Manuals added over one hundred new CPT codes for molecular pathology services. There are 92 Tier 1 codes for 2012 and 13 Tier 1 codes for 2013, which describe gene-specific and genomic procedures, and nine Tier 2 codes, which represent procedures not listed in the Tier 1 codes and which are arranged by the level of technical resources and interpretive work they require. (The Tier 2 codes include parenthetical examples of methodologies with general guidelines for procedures for a given code.)

ACLA acknowledges the tremendous task CMS has before it, given the large number of new codes and the complexity of the tests they represent. To help CMS determine the proper way to price the new codes, below, we set forth a brief history of Medicare payment for molecular pathology services and a summary of the statutory and regulatory provisions relevant to payment for molecular pathology services under the PFS. We then provide answers to specific questions asked by CMS in the Proposed Rule and our reaction to CMS's proposal to include all molecular pathology tests on one fee schedule. Finally, we comment on CMS's suggestion that it may revise 42 C.F.R. § 415.130, which describes current conditions for payment under the PFS for physician pathology services.

A. Molecular Pathology Services are not New Tests

As CMS acknowledges in the text of the Proposed Rule, the molecular pathology services represented by the new CPT codes are not new tests; it is only the *codes* that are new. CMS points out, "Molecular pathology tests are currently billed using a combination of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called 'stacking' because different 'stacks' of codes are billed depending on the components of the fundamental test. Currently, all of the stacking codes are paid through the

CLFS."[2] The stacking codes will be replaced as of January 1, 2013 with more specific codes, necessitating the exercise CMS is engaged in now to determine how to pay for these new codes that have replaced the stacking codes.

The new molecular pathology CPT codes are applicable to existing tests paid under the CLFS and permit the tests to be described with greater specificity and allow for gene- and analyte-specific information to be transmitted to payors. There is nothing about the tests or about the process that the American Medical Association CPT Editorial Panel used to develop the new codes that calls for a full-scale overhaul of payment for these existing tests that the new codes describe.

B. Statutory and Regulatory Background for Payment for Molecular Pathology Services under the Clinical Laboratory Fee Schedule and the Physician Fee Schedule

The authority for Medicare payment for molecular pathology tests and other clinical diagnostic laboratory tests under the CLFS can be found at 42 U.S.C. § 1395l(h). Regulations promulgated to implement that statutory provision set forth the process for setting payment rates. To determine the payment amount, "cross-walking" is used if it is determined that a new test or a substantially revised code is comparable to an existing test, multiple existing test codes, or a portion of an existing test code, and "gap filling" is used "when no comparable existing test is available."[3]

The regulation on payment of physician services under the PFS requires that a service meets all of the relevant criteria or it cannot be paid under the PFS. One of the specified conditions is that "the services ordinarily require performance by a physician."[4] In the case of laboratory services, the conditions set forth at 42 C.F.R. § 415.130 also must be met. In relevant part, clinical laboratory interpretive services furnished by a pathologist may be paid for under the PFS only if they are requested by the beneficiary's attending physician, if they result in a written narrative report included in the beneficiary's medical record, and if they require the exercise of medical judgment by the consultant physician.[5]

C. ACLA's Responses to CMS's Questions about Molecular Pathology Codes

In light of the existing regulatory framework for payment for pathologist services under the PFS, CMS asks the following questions about the molecular pathology codes:

1) Do each of the 101 molecular pathology CPT codes describe services that are ordinarily furnished by a physician?

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[2] *Id*. at 44,783.

[3] 42 C.F.R. § 414.508.

[4] 42 C.F.R. § 415.102(a). Additionally, the services must be performed personally for a Medicare beneficiary by a physician and they must contribute directly to the diagnosis or treatment of an individual beneficiary.

[5] *See* 42 C.F.R. §§ 415.130(b)(4), (c)(1, 3-4).

2) Do each of these molecular pathology CPT codes ordinarily require interpretation and report?

3) What is the nature of that interpretation and does it typically require physician work?

4) Who furnishes interpretation services and how frequently?

Do each of the 101 molecular pathology CPT codes describe services that are ordinarily furnished by a physician? No. For the tests represented by the new molecular pathology CPT codes, it is not possible to state categorically that each and every one of the services "ordinarily" is furnished by a physician. While the tests may be requested by physicians, they are performed by laboratories because they are clinical laboratory services. The tests represented by the new CPT codes ordinarily do not require the involvement of a physician, although, as we discuss below, in some instances a pathologist will be requested to perform the interpretation.

Who furnishes interpretation services and how frequently? A survey of ACLA's members shows that in most cases, the tests are performed, supervised, and interpreted by non-physicians, most often Ph.D.s with expertise in medical genetics. In some laboratories, some tests may be interpreted by physicians when a physician's input may be needed due to the results of the test. Among the 367,370 molecular pathology allowed services with interpretation and report billed and paid in 2010, approximately 80 percent of the services did not require a physician interpretation; only 20 percent of the services did require a physician interpretation.[6]

Do each of these molecular pathology CPT codes ordinarily require interpretation and report? What is the nature of that interpretation and does it typically require physician work? Yes, each of the tests represented by the new molecular pathology CPT codes ordinarily requires an interpretation and report, but the nature of that interpretation and report varies. For some tests, such as Factor V Leiden, the interpretation of the test yields a simple positive or negative result. However, for other tests, negative results require an expenditure of resources for interpretation because, for each area of a gene that is sequenced, the person performing the interpretation must confirm the findings. For other tests, such as that for Chronic Myelogenous Leukemia ("CML"), the interpretation determines to what extent the BCR-ABL transcript is present.

Regardless of the nature of the interpretation for a molecular pathology test, Ph.D. geneticists are qualified and credentialed to perform the interpretation. Both Ph.D. geneticists and pathologists can be certified in genetics by an American Board of Medical Specialties. For Ph.D. geneticists and pathologists specializing in molecular genetics, the American Board of Medical Genetics is the certifying agency and is one of the 24 specialty member boards of the American Board of Medical Specialties. The American Board of Medical Genetics describes someone who may be certified in clinical molecular genetics as an individual with a doctoral

[6] *See* 2010 Part B National Data Summary File, *available at*: http://www.cms.gov/apps/ama/license.asp?file=/NonIdentifiableDatafiles/Downloads/PartBNational2010.zip.

degree (M.D., D.O., or Ph.D.) who can correctly perform and interpret molecular analyses relevant to the diagnosis and management of human genetic diseases and who can act as a consultant regarding laboratory diagnosis of a broad range of molecular genetic disorders.[7] Those certified by the American Board of Medical Genetics must hold an M.D. or a Ph.D. in genetics, molecular biology, or a related field before entering an accredited training program.[8] Based on the board's criteria, Ph.D.s and pathologists both can be qualified to interpret molecular analyses. (Indeed, even the 2012 CPT manual, which is published by the American Medical Association, acknowledges that the interpretation may be done "by a physician or other qualified health care professional."[9])

D. ACLA Believes All Molecular Pathology Codes Should Remain on the Clinical Laboratory Fee Schedule with Additional Payment for Physician Interpretation through the Physician Fee Schedule

ACLA believes that all of the new molecular pathology CPT codes should remain on the CLFS. As we have stated, a physician interpretation and medical judgment ordinarily are not required for each and every one of the tests represented by the new molecular pathology CPT codes. Therefore, it would not be possible, under current rules, to place all of the tests on the PFS. However, ACLA believes that when a physician's medical judgment is required to interpret the results of a specific molecular pathology test, the interpretation service should continue to be reimbursable with a "-26" modifier valued under the PFS as a physician interpretive service and the test itself should continue to be reimbursable under the CLFS. In the Medicare Claims Processing Manual, CMS has specified a list of clinical laboratory tests, including nucleic acid probes, for which a physician interpretation may be billed by appending the "-26" modifier to the clinical laboratory code. For this subset of codes, a laboratory bills the test codes and is paid under the CLFS, and if there is an interpretation by a pathologist, the laboratory bills for that service, which is paid based on the price established under the PFS.[10]

Judging from the preamble to the Proposed Rule, there appear to be far too many unanswered questions for CMS to place any of the molecular pathology CPT codes on the PFS. CMS said it could not propose national payment rates without knowing the appropriate physician work RVUs and times relative to other similar services, the typical laboratory setting and batch size, and the current projected utilization of each of the services. Because of this lack of information and CMS's dissatisfaction with the quality of data it has, CMS said that if the codes were placed on the PFS, it would require Medicare contractors to price the codes. However, without clear guidance from CMS on the very topics about which the agency says its information is inadequate, contractor pricing likely would be variable, potentially inequitable, and rushed, given the short time period to price over one hundred codes (less than two months). In light of this, ACLA believes that the only prudent course for CY 2013 and beyond is for all of the codes

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[7] *See* http://www.abmg.org/pages/training_specialties.shtml.
[8] *See* http://www.abmg.org/pages/training_options.shtml.
[9] American Medical Association, 2012 CPT Professional Edition (2011) at 407.
[10] *See* Medicare Claims Processing Manual, Pub. 100-04, Ch. 12, Sec. 60.E. The professional component payment made in such an instance should be based on the recommendations of the Relative Value Scale Update Committee ("RUC"), which reviewed many of these codes in 2011 and 2012.

to be placed on the CLFS with the possibility of reimbursement through a modifier valued on the PFS for physician interpretation services in the cases when it is required.

The new molecular pathology codes are good candidates for cross-walking. CMS regulations state that cross-walking is appropriate when "it is determined that a new test is comparable to an existing test, multiple existing test codes, or a portion of an existing test code."[11] As we stated, these are existing tests that are being described with new codes. The new molecular pathology CPT codes represent tests that, in some cases, have been performed for two decades, and CMS contractors have significant payment and claims history and ample data to use as a guide for applying cross-walking principles. There is no statutory or regulatory requirement that would necessitate re-pricing the molecular pathology tests that are represented by new codes.

CMS should cross-walk the molecular pathology codes to fair intermediate price points based on historical pricing. Labs may perform these tests in slightly different ways; therefore, the stacking codes historically billed and the reimbursements received have differed somewhat from lab to lab (except for those tests provided by a sole-source laboratory). It is not possible for the majority of codes to determine which way of performing each test is "more right" or "more appropriate" than others, because the tests are complex and each laboratory has had to make its own determination about how it believes a test is best performed, with the requisite sensitivity and specificity. Therefore, for the majority of codes, there is no one code (or set of codes) that can provide accurate pricing guidance. We believe it is advisable for CMS to select a benchmark among the various data points that are available using the historical billing data for each test, such as the median price. Choosing the lowest or highest price paid would not be appropriate or fair. Choosing the median price would be equitable and relatively simple, and CMS has used this methodology in other contexts, such as when it establishes National Limitation Amounts for the CLFS. This approach also would ensure some consistency in pricing in 2013, which is especially important because of other negative reimbursement changes labs will experience in the coming year.[12]

The Tier 2 molecular pathology CPT codes (CPT codes 81400-81408) present a particular challenge. These codes include a generic code description, such as "Molecular pathology procedure, Level 1 (e.g., identification of a single germline variant [e.g., SNP] by techniques such as restriction enzyme digestion or melt curve analysis," followed by a non-exhaustive listing of tests that would meet that description. For these tests, payment could be based on a median price for all example tests associated with each code. The price may have to be revised in the future as additional example tests are added to each of the generic codes during the annual coding process.

[11] 42 C.F.R. § 414.508.

[12] These include a permanent productivity adjustment that will reduce laboratory payments below the rate of inflation, additional cuts of 1.75 percent annually from 2011 through 2015, a 2 percent annual cut pursuant to the anticipated sequestration, and an additional negative 2 percent rebasing of the CLFS as part of the Middle Class Tax Relief and Job Creation Act of 2012.

E. CMS Misunderstood ACLA's Position on Physician Interpretation of Tests

We note that in the preamble of the Proposed Rule, CMS appears to have misunderstood ACLA's position with respect to which tests are interpreted by a physician. It said, "The American Clinical Laboratory Association (ACLA) has indicated that 32 of 101 new molecular pathology codes are interpreted by a physician and that a physician may perform the technical component associated with 2 of the 101 CPT codes."[13] ACLA conveyed its position about pricing the molecular pathology tests to CMS in early May 2012. In addition to a written statement, ACLA shared with CMS a spreadsheet showing "New Molecular Diagnostic Codes for Which a Physician May Render a Clinical Interpretation."[14] The written statement said, "We included a separate list of those codes that ACLA members believe *may require a separate physician interpretation, in addition to the clinical laboratory service*."[15] ACLA did not say that the codes on the spreadsheet "are interpreted by a physician and that the physician may perform the technical component associated with 2 of the 101 CPT codes." Our position is that *if* physician work is involved in the interpretation, then payment for that service ought to be made with a modifier to the clinical laboratory services paid under the CLFS.

Additionally, the total number of codes addressed by ACLA concerning possible physician interpretation was 23 codes, not 32 codes. ACLA's spreadsheet included 18 Tier 1 codes and five Tier 2 codes (representing 10 tests). The two codes to which CMS refers in the Proposed Rule's preamble are codes that appear on ACLA's list of tests that may involve a physician interpretation that did not appear on the American Medical Association's list.[16]

F. Proposed Modification of 42 C.F.R. § 415.130

CMS said that if it determined that the codes should be paid under the PFS, it "would consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology services."[17] This indicates either that CMS believes that these tests do not meet the current requirements set forth at § 415.130 or that it cannot determine yet whether the tests do or do not meet those requirements. CMS has not said why it would consider including the new molecular pathology codes on the PFS if they cannot be accommodated by the current regulations, and ACLA asks that CMS publicly clarify its rationale for such an action before acting on it.

ACLA also is disappointed that CMS did not propose how it might modify the language of § 415.130 if it found such a modification to be necessary, and if CMS plans to do so, it must issue a proposed rule detailing the specific change(s) it intends to make so that we may comment on the proposed change, if any. (We note, also, that if CMS were to modify § 415.130 in order to accommodate molecular pathology tests, it also would have to modify § 415.102, since these tests do not "ordinarily require performance by a physician.") Under the Administrative Procedure Act ("APA"), it is well-established that an administrative agency that wishes to amend

[13] 77 Fed. Reg. 44,783.
[14] The list of codes is attached.
[15] Emphasis added.
[16] These are codes 81229 and 81260.
[17] 77 Fed. Reg. 44,785.

its governing regulations is required to provide sufficient notice of the proposed change, in order to allow for adequate public notice and comment.[18] CMS does not appear to intend to provide such notice and comment period relating to the suggestion that it would "consider modifying § 415.130 as appropriate," and such an amendment surely would violate the APA if it were done in the manner proposed by the agency.

G. Summary of ACLA's Position on Payment for Molecular Pathology Services

ACLA believes that all of the new molecular pathology CPT codes should remain on the CLFS because ordinarily they do not require the involvement of physicians and they typically are performed by qualified Ph.D. geneticists. In addition, laboratories should be able to bill for a physician interpretation under the PFS when the medical judgment of a physician is required for the results for a particular test. CMS has not articulated a compelling reason to move all of the molecular pathology test codes to the PFS from their current location on the CLFS, and ACLA believes they ought to remain on the CLFS, under which CMS can use cross-walking and establish a fair median price for each test.

III. Expiration of the "TC Grandfather" Payment for the Technical Component of Certain Pathology Services

Notwithstanding Congress' failure this year to extend the "TC grandfather" clause, ACLA requests that CMS implement the provision administratively. This clause historically has permitted independent laboratories to continue to bill Medicare for the technical component ("TC") of a service furnished to a hospital inpatient if the hospital had a prior arrangement with the laboratory for such service. In the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. 112-96, Congress acted to continue the payment only through June 30, 2012.

ACLA once again requests that CMS implement the "TC grandfather" provision on a permanent basis, as we do not believe the TC is included already in either the diagnosis-related group or hospital outpatient prospective payment system payment made to the hospital for the service. Implementing the provision on a permanent basis also would eliminate the billing issues that have occurred each time the provision has been set to expire.

IV. ICRs Regarding Diagnostic X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions

In the Collection of Information Section, CMS seems to have repeated, word for word, a section from the PFS Proposed Rule for CY 2011: "Proposed § 410.32(d)(2)(i) would require that the physician or qualified non-physician practitioner (as defined in § 410.32(a)(2)) who orders the service maintain documentation of medical necessity in the beneficiary's medical record. In addition, both the medical record and the laboratory requisition (or order) would be required to be signed by the physician or qualified non-physician practitioner who orders the service. The burden associated with these requirements would be the time and effort necessary

[18] 5 U.S.C. § 553(b).

for a physician or qualified non-physician practitioner to sign the medical record or laboratory requisition (or order)."[19]

We believe this to be a drafting error and request that CMS acknowledge it as such in the final rule. In the PFS Final Rule with Comment Period for CY 2012, CMS finalized its proposal to retract the policy that it had finalized in the PFS Final Rule with Comment Period for CY 2011, which had required a physician's or non-physician practitioner's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS.[20] ACLA maintains its longstanding objection to requiring a physician or non-physician practitioner's signature on each laboratory requisition or order because it would be unnecessarily burdensome for laboratories and would inconvenience patients and physicians with no material benefit to them.

V. In-Office Ancillary Services Exceptions

ACLA is disappointed that CMS once again did not include any discussion of the troubling practice of anatomic pathology self-referral arrangements that are abusing the "in-office ancillary services" or "IOAS" exception to the Physician-Self Referral law, or "Stark Law," under 42 C.F.R. § 411.355(b). Physician specialists increasingly are taking advantage of gaps in the anti-markup and self-referral rules and entering into business arrangements that permit them to order, bill, and be paid the full fee schedule rate for anatomic pathology services, even though the services are furnished by physicians who have little or no relationship with the ordering physician and/or his or her group. In past rulemakings, CMS has expressed concern about such arrangements, but it has not taken concrete steps to address them.

The original purpose of the IOAS exception was providing immediate, direct patient care in the office setting for the convenience of the patient. However, in the case of in-office pathology services, it is not uncommon for physician groups with in-office laboratories to bring in an outside physician who is available only once a week to review test results. Furthermore, if special stains are needed, there is no additional convenience afforded the patient, as the in-office laboratory must send those specimens to an outside laboratory. Without any added patient convenience, and in some cases, with an additional delay in processing specimens, the benefit of in-office pathology services is eliminated.

ACLA urges CMS, once again, to include a discussion of the abuse of the IOAS exception in the preamble to the PFS Final Rule and to follow up in the near-term with concrete and effective steps to curb or prevent such abusive practices. CMS's silence on abusive anatomic pathology self-referral arrangements may serve as a tacit signal to those engaged in such practices that the agency is unconcerned about them. ACLA looks forward to continuing to work with CMS and Congress on this issue.

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[19] *See* 75 Fed. Reg. 40,040, 40,224 (Jul. 13, 2010).
[20] *See* 76 Fed. Reg. 73,026, 73,301-73,304 (Nov. 28, 2011).

VI. Conclusion

Thank you for the opportunity to comment on these important issues.

Sincerely,

Alan Mertz

Alan Mertz, President
American Clinical Laboratory Association

Attachment: New MDx Codes for Which a Physician Many Render a Clinical Interpretation

NEW MDx CODES THAT MAY REQUIRE A CLINICAL INTERPRETATION

	2012 AMA Code	2012 AMA Description
1	81206	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
2	81207	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
3	81208	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative
4	81210	BRAF (v-raf murine sarcoma viral oncogene homolog B1) (eg, colon cancer), gene analysis, V600E variant
5	81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
6	81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (ITD) variants (i.e., exons 14, 15)
7	81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein) (eg, familial dysautonomia) gene analysis common variants (eg, 2507+6T>C, R696P)
8	81261	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplification methodology (eg, polymerase chain reaction)

9	81262	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); direct probe methodology (eg, Southern blot)
10	81263	IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis
11	81267	Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
12	81270	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
13	81275	KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis variants in codons 12 and 13
14	81301	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repari deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
15	81310	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants
16	81315	PML/RARalpha, (t(15;17)), (PML-RARA regulated adaptor molecule 1) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative

17	81341	TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using direct probe methodology (eg, Southern blot)
18	81342	TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
	81401 [Tier 2 Code]	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
19		ABL (c-abl oncogene 1, receptor tyrosine kinase) (eg, acquired imatinib resistance), T315I variant
	81402 [Tier 2 Code]	Molecular pathology procedure, Level 3 (eg, >10 SNPs, 2-10 methylated variants, or 2-10 somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and T-cell receptor gene rearrangements, duplication/deletion variants 1 exon)
20		TCD@ (T cell antigen receptor, delta) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population
	81403 [Tier 2 Code]	Molecular pathology procedure, Level 4 (eg, analysis of single exon by DNA sequence analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions, mutation scanning or duplication/deletion variants of 2-5 exons)
21		JAK2 (Janus kinase 2) (eg, myeloproliferative disorder), exon 12 sequence and exon 13 sequence, if performed
22		MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), exon 10 sequence

	81404 [Tier 2 Code]	Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)
23		EGR2 (early growth response 2) (eg, Charco-Marie-Tooth), full gene sequence
24		KIT (C-kit) (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, GIST, acute myeloid leukemia, melanoma), targeted gene analysis (eg, exons 8, 11, 13, 17, 18)
25		NRAS (neuroblastoma RAS viral oncogene homolog) (eg, colorectal carcinoma), exon 1 and exon 2 sequences
26		PDGFRA (platelet-derived growth factor receptor alpha polypeptide) (eg, gastrointestinal stromal tumor), targeted sequence analysis (eg, exons 12, 18)
27		RET (ret proto-oncogene) (eg, multiple endocrine neoplasia, type 2B and familial medullary thyroid carcinoma), common variants (eg, M918T, 2647_2648delinsTT, A883F)
	81405 [Tier 2 Code]	Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons)
28		TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons